UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

UNITED STATES OF AMERICA)
ex rel.)
SHARA AMBROSECCHIA)
Plaintiffs,)
v.)
)
ALAVEN PHARMACEUTICAL, LLC.,)
a subsidiary of Meda Pharmaceuticals, Inc.)
AMERICA HEALTH PACKAGING,)
a subsidiary of AmerisourceBergen, Inc.)
AMNEAL PHARMACEUTICALS, LLC.,)
BOCA PHARMACAL, INC.,)
BRECKENRIDGE PHARMACEUTICAL, INC.,)
a subsidiary of Corporacion Quimico)
Farmaceutica Esteve Sa)
CONTRACT PHARMACEUTICALS, LTD., NIAGRA,)
a subsidiary of Contract Pharmaceutical Ltd.)
COUNTY LINE PHARMACEUTICALS, LLC.,)
EXCELLIUM PHARMACEUTICAL, INC.,)
FAGRON, INC.,)
f/k/a Gallipot Incorporated,)
GLENMARK GENERICS, INC., USA,)
GOLDLINE LABORATORIES, INC.,)
also d/b/a IVAX Pharmaceuticals)
LASER PHARMACEUTICALS, LLC.,)
LEGACY PHARMACEUTICALS US, INC.,)
LLORENS PHARMACEUTICALS)
INTERNATIONAL DIVISION, INC.,)
MAGNA PHARMACEUTICALS, INC.,)
MARATHON PHARMACEUTICALS, LLC.,)
MEDISCA, INC.,)
PADDOCK LABORATORIES, LLC.,)
a wholly- owned subsidiary of Perrigo Co.,)
PERRIGO COMPANY, INC.,)
QUALITEST PHARMACEUTICALS,)
SDA LABORATORIES, INC.,)
THE HARVARD DRUG GROUP, LLC)
d/b/a MAJOR PHARMACEUTICALS,)
a subsidiary of Generic Drug Holdings, Inc.,)
UNITED RESEARCH LABORATORIES,)
a subsidiary of Pharmaceutical)
Holdings Corp.)
VIRTUS PHARMACEUTICALS, LLC.,)

4:12CV002164 RWS

Cause No._____
FALSE CLAIMS ACT
COMPLAINT

JURY TRIAL DEMANDED

WEST-WARD PHARMACEUTICAL CORP.)
a subsidiary of Eurohealth (USA), Inc.,)
WOMEN'S CHOICE PHARMACEUTICALS,)
)
Defendants.)

COMPLAINT

Shara Ambrosecchia ("Relator") brings this action on behalf of the *United States of America* ("United States") for treble damages and civil penalties arising from Defendants' violations of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"). Defendants submitted false records or statements to the United States through the Federal Center for Medicare and Medicaid Services ("CMS") and thereby caused false claims for payment to be made through Medicare, as well as through other government-funded healthcare programs, for unapproved, unsafe or ineffective drugs. Relator fully describes the conduct Defendants have engaged in, as set forth below.

I. Nature of the Case

1. The Medicare program, along with other government-funded healthcare plans, only provides prescription drug reimbursement for FDA approved drugs. The products identified herein are not approved by the FDA and have never been proven safe and effective. Nevertheless, Defendants reported false information to CMS regarding the regulatory status of these products, representing that they were "*safe and effective*" in order to make them ostensibly eligible for Medicare reimbursement, as well as for reimbursement through other government-funded healthcare programs.

2. This false information corrupted CMS's list of reimbursement-eligible drugs, which caused claims for ineligible products to be submitted to Medicare and other government-funded healthcare programs, through CMS, and led CMS to improperly pay reimbursement for such

ineligible drugs. Thus, CMS was induced to pay false claims, all in violation of 31 U.S.C. §§ 3729(a)(1)(A) and (B).

3. The Defendants violated the False Claims Act in one or more of the following respects:

(i) by knowingly and/or recklessly submitting false classification information concerning drugs which have not been FDA approved, and which have not been determined to be "*safe and effective*" for all indications, thereby causing false claims to be made;

(ii) by knowingly and/or recklessly causing the presentation of false claims by submitting the false information described herein.

4. The Defendants' FCA violations caused the federal government to pay substantial sums in false claims. Based on the nature of the misrepresentations made to CMS, there is reason to believe that false claims identical to those described herein were paid for years.

5. But for Defendants' express misrepresentations that their products were classified as *safe and effective* and were, therefore, reimbursement-eligible, the federal government would not have paid untold dollars in reimbursement claims and Defendants would not have had illegal access to the lucrative government-funded healthcare market.

6. The Defendants' unapproved drugs are not only ineligible for Medicare reimbursement coverage, their manufacture and sale violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), and subjects the Defendants to criminal penalties as well. *See* 21 U.S.C. § 331(d).

7. Defendants' submission of unapproved drugs for reimbursement through Medicare, as well as through other government-funded healthcare programs, is, therefore, doubly reckless and brazen.

8. Among other exclusionary markers, unless a product is legally required to carry a National Drug Code ("NDC") number and to list an FDA Approval Date, it is not eligible for Medicare reimbursement. 42 U.S.C. §1396r-8(k)(3). Because Medicare's payment system identifies products by those NDC numbers, certain Defendants created NDCs and/ or FDA approval dates for their unapproved drugs and so reported them to CMS. Without these rogue NDCs and falsified FDA approval dates, certain Defendants' unapproved drugs could never have infiltrated the government-funded healthcare programs' drug reimbursement system.

9. The Defendants knew, or reasonably should have known, that the unapproved drugs that are the subject of this Complaint were not eligible for Medicare reimbursement. The Defendants also knew that CMS would rely on their drug classification representations in maintaining the list of reimbursement-eligible prescription drugs; Defendants knew that the wrongful inclusion of unapproved drugs on that list would result in the submission and payment of false claims.

10. Thus, Defendants knowingly misrepresented the classification of certain unapproved drugs to make them appear eligible for reimbursement. This *qui tam* action also seeks to recover losses caused by false claims submitted to other federally funded healthcare programs, including but not limited to Medicaid, Veterans Administration and Federal Employees Health Benefit, to the extent applicable.

11. Each Defendant's liability is premised upon the knowing or reckless submission of false information to CMS, which misidentified unapproved drugs, which defendants manufactured and/or sold, as eligible for reimbursement through government-funded healthcare programs, like Medicare.

II. FEDERAL JURISDICTION AND VENUE

12. The acts proscribed by 31 U.S.C. § 3729, *et seq.*, and complained of herein, occurred in the Eastern District of Missouri and elsewhere. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732(a), as well as under 28 U.S.C. § 1345.

13. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this District and one or more of the acts proscribed by 31 U.S.C.§ 3729 occurred in this District.

14. The allegations contained in this action have not been the subject of a public disclosure pursuant to § 3730(e)(4)(A) of the FCA.

III. THE PARTIES

15. The United States funds the provision of medical care, including reimbursement for pharmaceutical products, for eligible individuals through government healthcare programs such as Medicare, Medicaid, Veterans Administration, Federal Employees Health Benefit and other agencies and programs (hereinafter "Government Healthcare Programs"), acting through CMS.

16. Relator is a resident of the State of Minnesota. She has over 10 years of experience in the pharmaceutical industry.

17. The Defendants, including any successor or assigns of each entity, are drug manufacturers, distributors, labelers and companies otherwise engaged in the sale of pharmaceuticals, including the sale of unapproved drugs; a substantial portion of the sales at issue were ultimately funded by government healthcare programs throughout the United States, like Medicare.

18. At all times material to this Complaint, all Defendants transacted substantial business with the State of Missouri, including business unrelated to the misrepresentations made

regarding unapproved drugs, described herein.

19. More complete descriptions of each Defendant are identified below:

A. Alaven Pharmaceutical, LLC., ("ALAVEN") is a registered limited liability company and operates its principal place of business at *200 Cobb Pkwy. North, Ste. 428 in Marietta, GA 30062-3559*; Alaven Pharmaceutical, LLC., is a subsidiary of *Meda Pharmaceuticals, Inc.*, a Delaware corporation owned by *Meda AB* in Solna, Sweden.

B. American Health Packaging ("AMERICAN HEALTH") operates its principal place of business at 2550 John Glenn Avenue, Suite A in Columbus, Ohio 43217. American Health Packaging is a subsidiary of *AmerisourceBergen*, an Ohio corporation.

C. Amneal Pharmaceuticals, LLC ("AMNEAL") is a New York limited liability company with its principal place of business located at *440 US Highway 22, Ste. 104, in Bridgewater, New Jersey 08807-2477.*

D. Boca Pharmacal, Inc. ("BOCA") is a Florida corporation with its principal place of business located at *3550 NW 126th Ave., in Coral Springs, Florida 33065-2402.*

E. Breckenridge Pharmaceutical, Inc. ("BRECKENRIDGE") is a Florida corporation with its principal place of business located at *1141 S. Rogers Circle, Ste. 3 in Boca Raton, Florida 33487-2789;* Breckenridge Pharmaceutical, Inc., is a subsidiary of foreign parent, *Corporacion Quimico Farmaeutica Esteve Sa* located in Barcelona, Spain.

F. Contract Pharmaceutical Limited Niagra, ("CONTRACT PHARMA") is a subsidiary of foreign, privately-held *Contract Pharmaceutical Ltd.* located at 7600 Danbro Crescent Mississauga, Ontario L5N 6L6 Canada; Contract Pharmaceutical Limited Niagra operates its principal place of business at *Branch 100 Forest Ave., in Buffalo, New York 14213.*

G. County Line Pharmaceuticals, LLC ("COUNTY LINE") is a Wisconsin limited liability company with its principal place of business located at *13890 Bishops Dr., Ste. 410 in Brookfield, Wisconsin 53005-6612.*

H. Excellium Pharmaceutical, Inc. ("EXCELLIUM") is a New Jersey corporation with its principal place of business located at *3g Oak Road in Fairfield, New Jersey 07004-2935.*

I. Fagron, Inc., ("FAGRON") formerly known as *Gallipot Incorporated* is a domestic Minnesota corporation (type of company) with its principal place of business located at *2400 Pilot Knob Road in St. Paul, Minnesota 55120.*

J. Glenmark Generics, Inc., USA ("GLENMARK") is a Delaware corporation with its principal place of business located at *750 Corporate Drive, in Mahwah, New Jersey 07430-2009.*

K. Goldline Laboratories, Inc., ("GOLDLINE"), also d/b/a *IVAX Pharmaceuticals*, is a Florida corporation with its principal place of business located at 4400 Biscayne Blvd., in Miami, Florida 33137.

L. Laser Pharmaceuticals, LLC., ("LASER") is a South Carolina limited liability company with its principal place of business located at *6003 Ponders Ct. in Greenville, South Carolina 29615-4601.*

M. Legacy Pharmaceuticals US, Inc., ("LEGACY") is a Delaware corporation with its principal place of business located at *959 S. Coast Drive Ste. 325 in Costa Mesa, California 92626.*

N. Llorens Pharmaceuticals International Division, Inc., ("LLORENS") is a Florida corporation with its principal place of business located at *6852 Northwest 77th Ct. in Miami,*

Florida 33166-2713.

O. Magna Pharmaceuticals, Inc., ("MAGNA") is a Kentucky corporation with its principal place of business located at 10801 Electron Dr., Ste. 100 in Louisville, Kentucky 40299.

P. Marathon Pharmaceuticals, LLC., ("MARATHON") is a Delaware limited liability company with its principal place of business located at *9 Parkway Blvd. North, Suite 175 in Deerfield, Illinois.*

Q. Medisca, Inc. ("MEDISCA") is a New York corporation with its principal place of business located at *661 Route 3, Unit C, Plattsburgh, New York, 12901-6531.*

R. Paddock Laboratories, LLC., ("PADDOCK") is a fully-owned subsidiary of *Perrigo Company, Inc.,* a Michigan corporation with its principal place of business located at *515 Eastern Ave. in Allegan, Michigan 49010.*

S. Perrigo Company, Inc., ("PERRIGO") a Michigan corporation with its principal place of business located at *515 Eastern Ave. in Allegan, Michigan 49010.*

T. Qualitest Pharmaceuticals ("QUALITEST") is a North Carolina company with its principal place of business located at 3241 Woodpark Blvd., Ste. A in *Charlotte, North Carolina 28206-4212.*

U. SDA Laboratories, Inc., ("SDA LABS") is a New York corporation with its principal place of business located at *280 Railroad Ave. Ste. 207 in Greenwich, Connecticut 06830-6338.*

V. The Harvard Drug Group, LLC., d/b/a Major Pharmaceuticals ("MAJOR"), is a Michigan Limited Liability Company with its principal place of business located at *31778 Enterprise Drive in Livonia, Michigan 48150*; The Harvard Drug Group, LLC., is a subsidiary of

Generic Drug Holdings, Inc., a Delaware corporation also located at *31778 Enterprise Drive in Livonia, Michigan 48150* .

W. United Research Laboratories ("UNITED") is a Pennsylvania corporation with its principal place of business located at *1100 Orthodox Street in Philadelphia, Pennsylvania 19124-3168;* United Research Laboratories is a subsidiary of *Pharmaceutical Holdings Corp.*, another Pennsylvania corporation, also located at *1100 Orthodox Street in Philadelphia, Pennsylvania 19124-3168.*

X. Virtus Pharmaceuticals, LLC., ("VIRTUS") is a Florida limited liability company with its principal place of business located at *2640 Causeway Center Dr. in Tampa, Florida 33619-6101.*

Y. West-Ward Pharmaceutical Corp. ("WEST-WARD") is a New Jersey corporation with its principal place of business located at *401 Industrial Way W. in Eatontown, New Jersey 07724-2209*; West-Ward Pharmaceutical Corp. is a subsidiary of *Eurohealth (USA), Inc.*, also located at *401 Industrial Way W. in Eatontown, New Jersey 07724-2209.*

Z. Women's Choice Pharmaceuticals, LLC ("WOMEN'S CHOICE") is an Arizona limited liability company with its principal place of business located at *219 South William Dillard Drive, Bldg. 3-123 in Gilbert, Arizona 85233-5526.*

20. At all times relevant hereto, Defendants acted through their agents and employees; the acts of Defendants' agents and employees were within the scope of their agency and employment. Upon information and belief, the policies and practices alleged in this Complaint were conducted on a regular, repeated and continuous basis, as a regular course of doing business over a substantial period of years.

21. Whenever this Complaint references any representation, act or transaction of any Defendant, Relator intends that such allegation encompasses the principals, officers, directors, employees, agents or representatives, while actively engaged in the course and scope of their employment, engaged in or authorized such representations, acts or transactions on behalf of each Defendant, deliberately ignored the truth or falsity of the information provided to CMS, Medicare and/or other government-funded healthcare programs, or acted with reckless disregard of the truth or falsity of such information.

IV. APPLICABLE LAW AND MEDICARE REIMBURSEMENT REQUIREMENTS

A. The False Claims Act

22. The False Claims Act provides that any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim, is liable for a civil penalty ranging from $5,000 up to $10,000 for each such claim, as adjusted by the *Federal Civil Penalties Inflation Adjustment Act of 1990*, (28 U.S.C. 2461 note; Public Law 104-410), plus three times the amount of the damages sustained by the Government. 31 U.S.C. §§ 3729(a)(1). A "claim" means any request or demand for money or property provided by the Government under one of its programs, such as Medicare. 31 U.S.C. §§ 3729(b)(2). Claims made to the states are actionable if the Federal Government will reimburse the state for any portion of the claim. 31 U.S.C. § 3729(b)(2)(A).

23. The Act allows *any person* having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. Based on these provisions, *qui tam* Relator seeks to recover all available damages, civil penalties, and other relief for the violations alleged herein.

B. The Food, Drug and Cosmetic Act

24. Under the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.,* drugs must be approved by the FDA for safety and effectiveness before they can be marketed. 21 U.S.C. § 355(a).

25. In order to qualify for Medicare reimbursement, the FDA must deem the drug to be *safe and effective*.

26. The use of unapproved, illegally-marketed drugs poses a serious health risk to patients, particularly Medicare recipients, many of whom are elderly and have extensive healthcare needs. It is particularly disturbing that the patients taking the unapproved drugs reasonably assume that the FDA approved the safety and effectiveness of the drugs they are taking. *See,* FDA Press Release dated June 8, 2006, *FDA Acts To Improve Drug Safety And Quality*.

27. Despite the risks involved, Defendants have a compelling financial incentive to participate in government-funded healthcare reimbursement programs, like that offered by Medicare, as it guarantees them access to a huge market segment wherein the U.S. government spends billions on prescription drugs each year.

C. Drug Reimbursement

28. Medicare provides drug reimbursement only for those drugs dispensed by prescription which are approved for safety and effectiveness by the FDA. 42 U.S.C. § 1396r-8(k)(2)(A).

29. In 1962, Congress amended the Federal Food, Drug and Cosmetic Act to provide greater regulation of drugs sold in the United States. Under those amendments, all new drugs must be shown by adequate studies to be both "*safe and effective*" before they can be marketed. Drugs approved as merely "safe" prior to 1962 (i.e. those approved between 1938 and 1962) had to be

reviewed as to their effectiveness under the Drug Efficacy Study Implementation ("DESI") program. A DESI review of over 3,400 drugs that entered the market between 1938 and 1962 was undertaken in the 1960s and 1970s. If the DESI review indicated a lack of substantial evidence of a drug's effectiveness for all of its labeled indications, the FDA published a Notice of Opportunity for a hearing concerning its proposal to withdraw approval of the drug for marketing. A manufacturer of that drug, or drugs "identical, related or similar" ("IRS") to that drug, could request a hearing and attempt to provide evidence of the drug's effectiveness. Drugs for which a Notice of Opportunity for hearing has been published are referred to as "less-than- effective" ("LTE" or "DESI-LTE") drugs, unless they receive FDA approval. The IRS counterpart of a DESI-LTE drug is also considered less than effective. "DESI drugs" deemed "Less Than Effective for *all* indications" are not eligible for reimbursement under government-funded healthcare programs, like Medicare.

30. Even if the FDA's final DESI determination classifies the drug product as effective for all or just some of its labeled indications, the drug and its IRS counterparts may only be marketed—and thus qualify for reimbursement—*if the manufacturer obtains FDA approval of a New Drug Application establishing the drug's safety and effectiveness for those indications*. All drugs in the DESI program, require FDA approval before marketing and reimbursement is permitted.

31. All FDA approved drugs are listed on the FDA's website (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm) as well as within *The Orange Book*, which contains the agency's published listing. Drugs that are not listed in either of those places are not approved by the FDA.

32. The drugs identified in this Complaint also fail to qualify for government healthcare reimbursement programs because they generally could not be prescribed for a "*medically accepted indication*" and are thereby excluded from the definition of a "Covered Outpatient Drug." 42 U.S.C.

§1396r-8(k)(3). A "*medically accepted indication*" is defined as "any use for a Covered Outpatient Drug which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." 42 U.S.C. §1396r-8(k)(6). Since the drugs identified in this Complaint are not FDA-approved, they are not included in the referenced compendia.

33. At all times, Congress and CMS have intended that *only FDA approved drugs* be eligible for reimbursement under federally-funded healthcare plans. Additionally, drugs that are approved only for Over-the-Counter use should not be classified as Medicare reimbursement-eligible since they are not approved for prescription use.

E. Manufacturers' False Drug Classifications in Reports to CMS Corrupt CMS' Database

34. In order to participate in government-funded healthcare reimbursement programs, Manufacturers must provide CMS with the proper code to identify their products in both their initial and Quarterly CMS Update Reports. The relevant DESI codes for drug classification are as follows:

2= Safe and effective;
3= Drug under review (no Notice of Opportunity for Hearing [NOOH] issued);
4= LTE/IRS drug for some indications;
5= LTE/IRS drug for all indications;
6= LTE/IRS drug withdrawn from market.

If a drug carries a code 5 or 6, it is categorically not eligible for reimbursement under healthcare programs like Medicare; Congress has expressly precluded payment for such drugs for decades. *See* 42 U.S.C. § 1396b (i)(5); 42 U.S.C. § 1395y (c); 42 C.F.R. § 441.25.

35. In order to become a participating Medicare provider, Defendants agreed to abide by all laws, regulations and procedures applicable to Medicare, including those governing reimbursement.

36. CMS requires manufacturers to provide a list of all their reimbursement-eligible drugs, identifying the drug's NDC number, product name, whether it is available by prescription or via over-the-counter (OTC), FDA approval date and the date the drug entered the market, and the Drug Efficacy Study Implementation (DESI) rating. Manufacturers are responsible for accurately reporting and updating their products' classification codes to CMS, subject to civil penalites. Over 500 manufacturers submit the requisite information concerning their drugs to CMS.

37. CMS requires that the list be updated quarterly (the "Quarterly Report"), in nearly all cases, the reports to CMS are submitted electronically, usually online. CMS uses the submitted information to compile and maintain a database identifying all the prescription drugs that are eligible for Medicare reimbursement or for reimbursement from another government-funded healthcare program.

38. To assist manufacturers in submitting accurate drug-related information, CMS periodically issues newsletters (called program releases), to manufacturers which contain additional information and instructions regarding the submission of drug data, including instructions related to products which are not eligible for reimbursement.

39. Based on industry statutes and regulations, none of the drugs identified in this Complaint are eligible for government-funded healthcare reimbursement, as they are either not FDA approved, or they only have approval for Over the Counter purposes, yet many of the Defendants falsely represented them as reimbursement-eligible in their Quarterly CMS Reports, submitted for the Second Quarter of 2012. Upon information and belief, similar representations

occurred as to all Defendants in additional CMS Reports over the past six years.

40. In compiling and maintaining its list of reimbursement eligible drugs, CMS relies upon and incorporates in the product information each manufacturer submits. Hence, when manufacturers falsely report classification codes related to their drugs, the misrepresentations subsequently corrupt the CMS list.

41. CMS electronically sends its list of reimbursement eligible drugs to the states each quarter where it is relied upon as the sole piece of information used to verify coverage and calculate rebates for various drugs, when reimbursement requests are submitted.

42. Despite their statutory obligation to truthfully report classification information pertaining to their drugs to CMS, when the Defendants submitted false FDA approval dates and false DESI status codes for their unapproved drugs, the false information made their ineligible products appear to be eligible for reimbursement through Medicare and other government-funded healthcare programs.

43. CMS and the State Governments, relied on the false information contained in the CMS Database and unwittingly paid claims for ineligible drugs. As to false information provided to CMS, each Defendants' name and the product(s) that were falsely classified either in the *2012 Second Quarter Report,* and/or upon information and belief, in multiple earlier CMS Quarterly Reports over the past six years, are specified below.

Labeler Name	**Item Description**
Medisca, Inc.	Isoxsuprine Hydrochloride
Women's Choice	Isometheptene

Perrigo	Trimethobenzamide suppositories
Goldline Laboratories, Inc.	Trimethobenzamide suppositories
American Health	Phenazopyridine HCl
Amneal Pharma.	Phenazopyridine HCl
Boca Pharma.	Phenazopyridine HCl
Contract Pharma.	Phenazopyridine HCl
SDA LABS	Phenazopyridine HCl
County Line	Hydrocortisone Acetate Suppositories
Paddock Labs	Hydrocortisone Acetate Suppositories
Laser Pharma.	Donatussin Syrup
Alaven Pharma.	Epifoam
Virtus Pharma.	Hyoscyamine
Breckenridge Pharma.	Hyoscyamine
Contract Pharma.	Hyoscyamine Sulfate
Major Pharmaceuticals	Hyoscyamine Sulfate
Paddock Labs	Hyoscyamine Sulfate
Gallipot	Belladonna Tincture
Legacy Pharma.	Belladonna Alkaloids w/ Phenobarbital
West-Ward	Belladonna Alkaloids w/ Phenobarbital
Excellium Pharmaceutical	Belladonna Alkaloids w/ Phenobarbital
Qualitest	Belladonna Alkaloids w/ Phenobarbital
Paddock	Belladonna & Opium Suppositories
Boca Pharma.	Pediahist
Magna	Stahist
Paddock Labs	Podophyllum in Benzoin Tincture
Llorens Pharma.	Tusnel
Marathon Pharma.	Amytal

Paddock Labs	Morphine Sulfate Suppositories
Paddock Labs	Hydromorphone HCL Suppositories
Glenmark	Morphine Oral Solution
Paddock Labs	Morphine Oral Solution
Paddock Labs	Bisacodyl Suppositories
Qualitest	Chlordiazepoxide/Clidinium
United Research Laboratories	Chlordiazepoxide/Clidinium/Bromide
Paddock Labs	Opium Tincture
Perrigo	Polyethylene Glycol 3350 (4.1 oz.; 8.3 oz.; 17.9 oz.) OTC Drug; should not be listed for Medicare reimbursement
Paddock Labs	Polyethylene Glycol 3350 Powder for Oral Solution OTC Drug; should not be listed for Medicare reimbursement

V. CAUSES OF ACTION

44. Relator specifically realleges and incorporates by reference paragraphs 1 - 45 as though fully set forth herein.

45. Based on information and belief, Relator brings four claims, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733, against Defendants for knowingly presenting or causing the presentment of false claims to the United States and state government Medicare and similar programs, from at least the 6 years preceding the filing of Relator's initial Complaint through the present.

46. Based on information and belief, in each instance, by virtue of the false records or false statements made by Defendants in violation of 31 U.S.C. § 3729(a)(1)(B), or the false claims which Defendants presented or caused to be presented in violation of 31 U.S.C. § 3729(a)(1)(A), the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and not more than $10,000 as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. 28 U.S.C. 2461 note; Public Law 104-410.

FIRST CAUSE OF ACTION

Making or Using False Records or Statements Material to False or Fraudulent Claims
(31 U.S.C. § 3729(a)(1)(B))

47. Upon information and belief, all Defendants knowingly made and/or used false records or statements – i.e., the false records or statements made by Defendants to CMS misrepresenting their unapproved drugs as Medicare reimbursement-eligible drugs, material to false claims. Based on information and belief, the Defendants intended the false statements or records to be material to the decision of the United States to pay the false claims.

48. Upon information and belief, in violation of 31 U.S.C. §3729(a)(1)(B), the Defendants knowingly and directly submitted to the UNITED STATES, through CMS, in their Medicare Reimbursement Agreements, their Quarterly CMS Update Reports and other documentation, false information as to the status of their products as eligible for reimbursement, their FDA approval dates, and/or DESI status code. Based on the Defendants' inclusion of false information in such documentation, they purported to qualify the unapproved drugs as eligible for reimbursement through Medicare and other similar programs. The UNITED STATES and state governments relied on this information, and the Medicare program paid claims for said unapproved drugs. In turn, the UNITED STATES was damaged since it paid funds in direct reimbursement for those unapproved drugs.

SECOND CAUSE OF ACTION

Causing False Records or Statements to be Made Which Are Material to False or Fraudulent Claims

(31 U.S.C. § 3729(a)(1)(B))

49. Upon information and belief, all Defendants knowingly caused to be made or used, false records or statements – i.e., through the use of the false records or statements made by the Defendants to CMS misrepresenting their unapproved drugs as reimbursement-eligible, material to false claims. Based on information and belief, the Defendants intended the false statements or records to be material to the decision of the United States to pay the false claims.

50. Upon information and belief, in violation of 31 U.S.C. §3729(a)(1)(B), the Defendants have knowingly and directly caused the UNITED STATES, to pay funds in reimbursement of unapproved drugs inasmuch as the states submitted *Quarterly Statements of Expenditures for Medical Assistance Programs* each quarter, and the UNITED STATES, relying on the Defendants' Quarterly CMS Update Reports, and other documentation and false information as

to the status of their products as reimbursement-eligible, such as, their FDA approval dates, and/or DESI status codes, paid the claims asserted. In turn, the UNITED STATES was damaged since it paid funds to the states in direct reimbursement for those unapproved drugs.

THIRD CAUSE OF ACTION

Causing The Presentation of False Claims For Payment or Approval
(31 U.S.C. § 3729(a)(1)(A))

51. Upon information and belief, in violation of 31 U.S.C. §3729(a)(1)(A), all Defendants knowingly and directly caused the submission of false claims, as they submitted to the UNITED STATES, through CMS, in their Reimbursement Agreements and their Quarterly CMS Update Reports, and other documentation, false information as to the status of their products as reimbursement eligible, such as, their FDA approval dates, and/or DESI status.

52. Based on information and belief, the Defendants' inclusion and misclassification of the unapproved drugs in such documentation, these products became ostensibly eligible for Medicare reimbursement and therefore physicians, pharmacies and other providers submitted claims to the Medicare program for the Unapproved drugs and Non-Drugs. Further and alternatively, upon information and belief, the Defendants caused false claims through the prohibited promotion and labeling of the unapproved drugs which were promoted and/or labeled as if they were appropriate for coverage or reimbursement under Medicare and similar programs, when they were not.

53. Based on information and belief, the Defendants knowingly caused to be presented false or fraudulent claims for Unapproved drugs to the United States.

FOURTH CAUSE OF ACTION

Causing the Presentment of False Claims For Payment or Approval
(31 U.S.C. § 3729(a)(1)(A))

54. Based on information and belief, in violation of 31 U.S.C. § 3729(a)(1)(A), all Defendants have knowingly caused the submission of false claims to the UNITED STATES through information provided to CMS, including their Quarterly CMS Update Reports, by falsely certifying

that all drugs paid for were in compliance with federal law. Upon information and belief, Defendants caused states to submit said false claims by their acts of submitting false information to the UNITED STATES, through CMS, in their Quarterly CMS Update Reports and other documentation, as to the status of their products as reimbursement-eligible, their FDA approval dates, and/or DESI status codes. Based on the specified Defendants' inclusion of false information in such documentation, they purported to qualify the unapproved drugs for reimbursement.

55. Based on information and belief, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval of their unapproved or misclassified drugs to the United States.

WHEREFORE, and for all the foregoing reasons, Relator respectfully requests this Court to enter Judgment against Defendants, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims asserted over a period of six years prior to the filing date of this Complaint, alleged herein, as provided by the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq*.

(b) That the maximum civil penalties be imposed for each and every false claim that Defendants presented or caused to be presented under the Federal False Claims Act over a period of six years prior to the filing of this Complaint.

(c) That pre-judgment and post-judgment interest be awarded, along with reasonable attorney's fees, costs, and expenses, which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant the Federal False Claims Act.

(e) That this Court award such other and further relief as it deems proper.

JURY DEMAND

Pursuant to Rule 38 of *The Federal Rules of Civil Procedure*. Relator hereby demands a trial by jury in this case on all issues so triable.

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